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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,990	01/30/2004	Borje Sellergren	1876.115US1	1989
21186 7590 09/08/2009 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER KOSAR, ANDREW D	
			ART UNIT 1654	PAPER NUMBER
			NOTIFICATION DATE 09/08/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
request@slwip.com

Office Action Summary	Application No. 10/707,990	Applicant(s) SELLERGREN ET AL.	
	Examiner ANDREW D. KOSAR	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments/Amendments

Applicant's arguments and amendments filed April 28, 2009 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

With regards to the anticipatory rejection, Applicant has amended the claim to recite that the peptide corresponds to an epitope of a target peptide or protein where the epitope is a peptide that corresponds only to a part of the target peptide or protein and argues that Mosbach does not teach using epitopes (a part of a full length peptide/protein). Applicant argues that Mosbach does not disclose the use of a peptide epitope of a target protein/peptide. Respectfully, as above, insulin is an epitope of preproinsulin, and thus still anticipates the claims. Furthermore, trypsin is an epitope of the inactive trypsinogen.

With regards to the obviousness rejection, and in contrast to applicant's current assertions, as discussed and rebutted previously, Applicant stated clearly on the record that the peptides were obvious variants in the election of June 6, 2005, and restated on July 6, 2005. Applicant's new arguments merely provide new interpretations of Applicant's statements made on the record. For example, the election clearly states, "Responsive to the election requirement for a single peptide as among those set forth in claims 2, 4 and 9, Applicants do not maintain that these variants are patentably distinct," "the method ... is patentable irrespective of the support used" and "...irrespective of the support used." There is no other interpretation than Applicant admitting on the record that the variables are obvious variants of each other. Furthermore, the Examiner provided the identification that the species were not patentably distinct in the first non-

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final Office Action of January 5, 2006. In Applicant's reply of May 4, 2006, Applicant presents no traversal or arguments regarding the withdrawal of the restriction and the determination that the species were obvious variants. It is not until the reply of September 11, 2008 that Applicant first "clarifies" the remarks of June 6, 2005 by interpreting it to mean the compounds "may be patentably distinct". As previously, the new arguments that the statement does not admit on the record the species are not patentably distinct is unpersuasive.

For these, and the reasons of record, the rejections of claims 1-6 are maintained below.

Election/Restrictions

Claims 7-9 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on October 7, 2005 and July 6, 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5 and 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by MOSBACH (US Patent 6,489,418 B1).

The instant claims are drawn to synthesis of a molecularly-imprinted material (MIM), also known in the art as molecularly-imprinted polymers (MIP), comprising the steps of binding the peptide to a surface modified support, polymerizing monomers, e.g. acrylamides and/or methacrylates, using heat, UV, or a crosslinking agent, e.g. AIBN, and removing the support/peptide (dissolve/degrade) to generate the free MIM.

Mosbach teaches a general synthesis of a MIM in Example 3 (column 5) where trypsin is immobilized on agarose beds, and monomers are polymerized with a crosslinker and the agarose beads are dissolved with addition of an acidic solution.

In Example 4 (column 5), Mosbach further teaches attachment of insulin to a surface-modified silica surface, which has been modified to have N-hydroxysuccinimide esters as pendant groups. As discussed in previous Office Actions, attachment of insulin to the silica is equivalent to 'synthesis', given that Applicant's specification includes attachment of an amino acid to the surface as 'synthesis'. Imprinting is conducted with either a methacrylate/ styrene/ acrylamide/ bisacrylamide solution with the photoinitiator being methylene blue, or with VBIDA, MAA and EGDMA with AIBN as the initiator. The imprint is "a stable film which can be separated from the surface on which it has been formed, e.g. manually or by dissolution." (column 5, lines 65-67). Figure 6 provides a complementary scheme of the synthesis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over MOSBACH, as applied to claims 1-3, 5 and 6, *supra*.

Mosbach teaches a general synthesis of a MIM in Example 3 (column 5) where trypsin is immobilized on agarose beds, and monomers are polymerized with a crosslinker and the agarose beads are dissolved with addition of an acidic solution.

In Example 4 (column 5), Mosbach further teaches attachment of insulin to a surface-modified silica surface, which has been modified to have N-hydroxysuccinimide esters as pendant groups. As discussed in previous Office Actions, attachment of insulin to the silica is equivalent to 'synthesis', given that Applicant's specification includes attachment of an amino acid to the surface as 'synthesis'. Imprinting is conducted with either a methacrylate/ styrene/ acrylamide/ bisacrylamide solution with the photoinitiator being methylene blue, or with VBIDA, MAA and EGDMA with AIBN as the initiator. The imprint is "a stable film which can be separated from the surface on which it has been formed, e.g. manually or by dissolution." (column 5, lines 65-67). Figure 6 provides a complementary scheme of the synthesis.

Mosbach teaches the method for is usable for enzymes, antigens, and antibodies (e.g. claim 17).

Because Applicant has admitted on the record that there is no patentable distinction between the peptide epitope of claim 2 and the species recited in claim 4, it would have been obvious to have used any peptide, including those recited, in practicing the method. Additionally, because Applicant has admitted that the method is patentable "irrespective of the support used" and "irrespective of the [monomer] mixture used", it would have been obvious to

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have used any monomer mixture and any support, including those recited, in practicing the method. One would have been motivated to use any peptide, as Applicant has stated that there is no patentable distinction, and because Mosbach teaches you can use any peptide. One would have been motivated to use any support and monomer mixture, as Applicant has stated that there is no patentable distinction, and because Mosbach teaches using monomers and supports. One would have a reasonable expectation for success in practicing the method, as MIP synthesis is widely practiced in the art, and Applicant states that the method can be practiced with any peptide, support and monomer mixture because they are not patentably distinct from one another.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 7-9 drawn to an invention nonelected without traverse in the reply filed on June 6, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654